Remarks

The claims have been amended to relate to an antimicrobial composition free of halogenated compounds. The halogenated compounds are considered as being environmentally undesirable. In addition, the complexes of the present invention have been allowed to be used around food without being rinsed away and have been approved by the FDA for such use. It is believed to be the only sanitizer approved for such use.

Reconsideration is respectfully requested of the rejection of the claims as now amended under 35 USC 102(b) or alternatively under 35 USC 103(a) in view of Smith.

Smith is distinguished from the compositions of the present invention several ways. Smith utilizes an antimicrobial compound containing halogen groups which are environmentally undesirable. Moreover, the compounds are toxic and cannot be used around food without the additional step of washing the surfaces to remove the complex. The complexes formed require the addition of a lactam or lactone to obtain a long lasting effect. It has been found that the lactones and lactams have a short shelf life and oxidize and not only discolor but precipitate out of solution.

Smith and the present applicants have the same assignee, AlphaMed Pharmaceutical Corp. The present invention is an improvement over Smith by providing a more stable composition which is non-toxic and can be used around food.

According to the present invention, the anti-microbial composition provides long lasting protection, namely, at least 28 days without the requirement of a lactone or lactam or polymer.

It has been found that the present complexes do not leach out of different polymers. For example, in a slightly water soluble hydroxyl cellulose film, the film surface is rejuvenated as the polymer slowly dissolves in water, namely rain. This has resulted in coated wire mesh used around chickens to reduce the occurrence of salmonella.

In a separately filed patent application, the composition is encapsulated within a cellulosic sponge mop. The antimicrobial is not used to dispense on a floor but to kill the microorganisms which remain on the mop during storage to prevent degradation and the formation of odors.

Consequently, Smith does not on all four corners teach the presently claimed composition so that the rejection under 35 USC 102(e) should be removed. Also, the presently claimed invention provides an unexpected advantage over Smith by being more stable, can be used around food without washing and is environmentally acceptable.

Smith does not make obvious the presently claimed invention under 35 USC 103(a) since Smith does not form a stable solution. Smith proposes complexing the phenol with the lactam or lactone. Additionally, applicants' amine compound is different so that it can be used around food. Applicants do not use halogenated compounds and achieve the same or better results than the compositions of Smith. Applicants' assignee originally sold the compositions of Smith but discovered that after six months, sludge formed. This led to the present invention.

Smith is also silent about incorporating the composition in a polymer such as an acrylic polymer or a cellulosic polymer. The lactones and lactams were unstable.

Consequently, the presently claimed invention provides a patentable distinction over Smith.

Reconsideration is respectfully requested of the rejection of the claims under 35 USC 103(a) as being unpatentable over Merchant et al in view of Wakoa et al and Dellian et al.

Dellian et al is not pertinent to the present invention since applicants' object is to use a fragrance such as limonene which is also anti-microbial. In addition, Dellian is silent with regard to a fragrance for an amine compound.

Merchant et al does not teach the use of the presently claimed diamine so that Merchant et al does not provide a composition for use against both gram-positive and gram-negative microbes. Merchant et al does not teach the complexes formed in the presently claimed composition which includes a complex between the amine compound and phenol or the amine compound and a dicarboxylic acid.

Wakao et al does not add anything to the teaching or Merchant et al which would lead to the present invention. The nonyl phenol is primarily a surfactant which has an anti-viral effect. It does not complex with the amine. There are no dicarboxylic acids which are intended to complex with the amines. The amines of Wakao are not the same as presently claimed. The antimicrobial agents of Wakao are intended to leach out of the polymer to provide the protection of the sea structure. In contrast, the anti-microbials of the present invention are intended to stay within the polymers because of the complexes formed to prevent degradation or odor on a structure (mop) on which it is used.

Both Merchant et al and Wakao et al are silent with regard to the formation of complexes. In the present invention a complex is formed between the amine and the phenol compound as well as with the dicarboxylic acid.

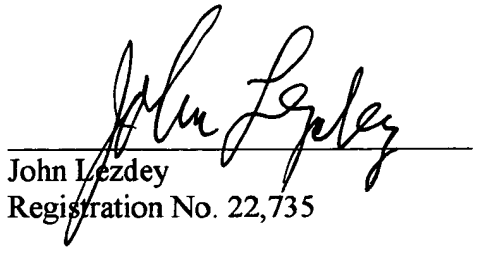
Consequently, Merchant et al, Wakao et al and Dellian et al fail to teach an antimicrobial composition defined by a series of different complexes which is stable, gram positive and gram negative, which can be used around food, and will not leach out from an acrylic polymer.

Submitted are test data which shows the long lasting anti-microbial effect of the present composition. Also, the FDA approval for use around food.

Reconsideration and favorable action are earnestly requested in view of the foregoing.

If there are any outstanding issues, the Examiner is requested to telephone the undersigned.

Respectfully submitted,
JOHN LEZDEY & ASSOCIATES



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Consumer Product Testing Co.

MICROBIOLOGY DEPARTMENT

FINAL REPORT

Study Number M95-207

COMPARATIVE EVALUATION OF STABILITY OF ANTIMICROBIAL EFFECTIVENESS OF SURFACE CLEANER / DISINFECTANTS

SPONSOR: **BETTER WORLD DISTRIBUTORS**

CONTACT: Ms. Jessica Godshall
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Analytical Chemistry • Microbiology

COMPARATIVE EVALUATION OF STABILITY OF ANTIMICROBIAL EFFECTIVENESS OF SURFACE CLEANER / DISINFECTANTS

OBJECTIVE: To determine the relative antimicrobial effectiveness of candidate surface cleaner / disinfectants over a four week period. This method was designed and is intended for obtaining basic information about the relative stability of the formulations tested. It is not intended for demonstration or satisfaction of official performance requirements.

SPONSOR: **BETTER WORLD**

CONTACT: Ms. Jessica Goddard
Chemical Engineer

STUDY DIRECTOR: David A. Reifsnyder
Director, Microbiology Department

TESTING FACILITY: Microbiology Laboratory
10 Industrial Road
Fairfield, New Jersey 07004

TEST MATERIALS: Three cleaning / disinfecting solutions, coded Product A, B and C.

Identification: Test materials were identified by Consumer Product Testing Company, Inc. (C.P.T.C.) study numbers:

M95- 267.01 (Product A),
M95- 267.02 (Product B),
M95- 267.03 (Product C).

TEST DATES: The study was conducted as detailed in the procedural outline (i.e. per proposed protocol) below. the study was initiated on the week of March 13, 1995 with subsequent runs on 3/31/95 and 4/13/95 (days 14 and 28 after the initial evaluation).

DEVIATIONS: The following deviation from the original Protocol was necessary in STUDY DESIGN step 4)i):

In pre-test trials with 5 uL of inoculum alone, drying of the inoculum on the test piedgets had taken about 3 minutes. On running the test, with test product applied first, drying took ~20 minutes. This was likely due to hygroscopicity on the part of the dried test sample. Since the sponsor had requested that the sample piedgets be timed after drying, subculture was carried out at 10 and 15 minutes after apparent drying of the sample / inoculum. This practice was continuous throughout the study and, where a killing / concentration gradient was observed, a test system for obtaining comparative results was apparently achieved.

The Protocol indicates a 24 - 48 hour incubation period, however it was observed that several broth cultures were growing out after the assigned period. Positive growth from 72 and /or 96-hour incubation were therefore included in the interpretation of results. Such growth is indicative of surviving / proliferative organisms and therefore gives information about the relative antimicrobial activities of the product / time periods.

STUDY DESIGN:

The study will be conducted according to GENERAL PROCEDURE FOR DETERMINATION OF PRODUCT MINIMUM INHIBITORY AND MINIMUM LETHAL CONCENTRATIONS (previously issued to sponsor) with the following additions and amendments:

1) The test organism / strain is specified as *Pseudomonas aeruginosa* ATCC 9027.

Two consecutive 24-hour Trypticase Soy Broth (TSB) cultures will be prepared, the second diluted with (TSB) to prepare an inoculum containing approximately 10^7 cells per milliliter.

2) The test solution dilutions will be prepared using sterile deionized water, per Sponsor directive, the dilution schema will be:

Sample Code								
A:	2%	1.5%	1.0%	0.75%	0.5%	0.25%	0.125%	0.0625%
dilute:	as is	1:1.33	1:2	1:2.667	1:4	1:8	1:16	1:32
B:	2%	1.5%	1.0%	0.75%	0.5%	0.25%	0.125%	0.0625%

3) Test samples of "treated surfaces" will be prepared using Formica pledgets approximately 0.75 cm^2. Each trial solution / dilution will be applied at 50 µL onto each of six pledgets, two for each test interval, one for each time period trial (10 and 15 minutes). The solutions were allowed to air dry forming a treatment film on each pledget. Each dilution's set of 6 pledgets will be placed in a sterile petri dish, covered for the duration of the test. Bacterial challenges will be performed on pledgets in the petri dish.

4) At each time interval (Time 0, 14 and 28 days) one pledget pair of each product/dilution will be tested as follows:

i) A 5µL aliquot of the *Pseudomonas aeruginosa* suspension is placed at the approximate center of each pledget, and allowed to air dry; this takes about 3 minutes

Post - test note: See DEVIATIONS In STUDY DESIGN step 4) I) -

ii) After 10 minutes, one pledget will be aseptically transferred to a tube of Trypticase Soy Broth (TSB).

iii) After 15 minutes, the second pledget will be aseptically transferred to a second tube of Trypticase Soy Broth (TSB).

iv) The TSB / pledgets are then incubated at 30 - 35 °C for 24 - 48 hours, then examined for growth.

5) The data gathered from the study will be tallied on the attached DATA / REPORT SHEET. The relative antimicrobial activity of each product dilution at 10 and 15 minute exposure times will then be assessed and any reduction in activity over the twenty-eight day test period realized.

RESULTS: See appended Data / Report sheets

Lethality of formulation *vs P. aeruginosa* A.T.C.C. 9027; a (NEG) result indicates lethality, a " + " denotes organism growth in initial broth and / or subculture.

Time 0

Dilution	10 min	15 min
2%	NEG	NEG
1.5%	NEG	NEG
1.0%	NEG	NEG
0.75%	NEG	NEG
0.50%	NEG	NEG
0.25%	NEG	NEG
0.125%	+	+
0.0625%	+	NEG

Day 14

Dilution	10 min	15 min
2%	NEG	NEG
1.5%	NEG	NEG
1.0%	NEG	NEG
0.75%	NEG	NEG
0.50%	NEG	NEG
0.25%	NEG	NEG
0.125%	NEG	NEG
0.0625%	NEG	NEG

Day 28

Dilution	10 min	15 min
2.0%	NEG	NEG
1.5%	NEG	NEG
1.0%	NEG	NEG
0.75%	NEG	NEG
0.50%	NEG	NEG
0.25%	NEG	NEG
0.125%	NEG	NEG
0.0625%	NEG	NEG

Analyst: [redacted]

Reviewed / Approved by: [redacted]

08/23/00 Reference Files System

Product Data Report

Identification Number: 69658-3 Case Barcode: 046768

Product Name: NOVIGARD (QUICK DRY)

Case Type: R Federal Registration

Company: 69658 ALPHAMED PHARMACEUTICAL, CORPORATION

Product Manager: 34 Adam Heyward
Product Status: A Active
Cancel/Transfer Reason:

Formulation Code: 16 Ready-to-Use Solution
Toxicity Category: 2 Warning
RCRA Classification: Not Available

Label Date: 97/05
Approval Date: 05/15/97
Cancellation Date: / /
Stocks Date: / /

Transferred: No
Suspended: No

Use Categories		Pest Categories
Terrestrial Food Crop:	No	
Non-Pest:	No	
Terrestrial Feed Crop:	No	
Disinfectant:	Yes	
Terrestrial Non-Food Crop:	No	
Fungal:	No	
Aquatic Food Crop:	No	
Invertebrate:	No	
AquaticNon-Food Outdoor:	No	
Nematodal:	No	
Aquatic Non-Food Residential:	No	

Plant: No
Aquatic Non-Food Industrial: No
Vertebrate: No
Greenhouse Food Crop: No
Greenhouse Non-Food Crop: No

Flags

Forestry: No
ResidentialOutdoor: No
Restricted Use: No
Indoor Food: Yes
Conditional Use: Yes
Indoor Non-Food: Yes
Reregistration: No
Indoor Residential: Yes
Packaging: No
Indoor Medical: Yes
Special Review: No

Miscellaneous

Child Resistant